Research Highlights

Highlights from the latest articles in primary percutaneous coronary intervention and coronary vein graft bypass interventions

Primary percutaneous coronary intervention: door-to-balloon time and mortality

Evaluation of: Menees DS, Peterson ED, Wang Y *et al.* Door-to-balloon time and mortality among patients undergoing primary PCI. *N. Engl. J. Med.* 369(10), 901–909 (2013).

In patients presenting with acute ST-segment elevation myocardial infarction, the American College of Cardiology/American Heart Association give a class I recommendation for primary percutaneous coronary intervention (PCI), with a door-to-balloon time of less than 90 min. The purpose of this study was to determine whether a decreased delay in door-to-balloon time was associated with mortality benefit.

The study was a retrospective observational study analyzing data from the CathPCI Registry® of 96,738 patients undergoing primary PCI for ST-segment elevation myocardial infarction from July 2005 through June 2009 at 515 hospitals. Data for 30-day mortality were obtained by subgroup analysis using a linked Medicare data set.

The study group was predominately comprised of men (72%) with a mean age of 60.8 years. Other baseline characteristics included the prevalence of hypertension (61%), dyslipidemia (59.2%), diabetes (18.8%) and smoking (43.3%).

Median door-to-balloon time decreased from 83 min in 2005–2006 to 67 min in 2008–2009 ($p < 0.001$). The percentage of patients with a door-to-balloon time less than 90 min improved from 59.7 to 83.1% over the course of the study ($p < 0.001$). Despite the decrease in delay to intervention, there was no mortality benefit observed over the course of the study, with in-hospital mortality of 4.8% in 2006 and 4.7% in 2009 ($p = 0.43$). There was also a trend of no mortality benefit in a prespecified subgroup analysis of patients >75 years old, patients in cardiogenic shock and patients with anterior myocardial infarction. Mortality benefit was only demonstrated when comparing patients with a door-to-balloon time of less than 90 min versus greater than 90 min (3.7 and 7.3%, respectively; $p < 0.001$).

The authors conclude that a further decrease in door-to-balloon time from the standard of less than 90 min is not associated with a 30-day mortality benefit. However, long-term mortality benefit has yet to be determined.

Treatment of nonculprit lesions during primary percutaneous coronary intervention

Evaluation of: Wald DS, Morris JK, Wald NJ *et al.* Randomized trial of preventive angioplasty in myocardial infarction. *N. Engl. J. Med.* 369(12), 1115–1123 (2013).

In patients with ST-segment elevation myocardial infarction and multivessel coronary artery disease, it is unknown whether or not to treat the nonculprit lesions at the time of revascularization of the culprit vessel. The PRAMI trial was designed to determine

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whether preventative PCI for nonculprit lesions would reduce outcomes of cardiac death, myocardial infarction or refractory angina.

This was a single-blinded, randomized trial enrolling 465 patients at five hospitals in the UK. Consecutive patients with acute ST-segment elevation myocardial infarction and multivessel coronary artery disease were enrolled. Patients were included if they had stenosis of 50% or more in a noninfarct artery. After randomization, all decisions to treat patients were left to the physicians' discretion. Stage PCI was discouraged. Patients presenting with refractory angina required objective evidence of ischemia. Patients were followed up for a mean of 23 months. The study was ended early on the recommendation of the Data and Safety Monitoring Committee based on highly significant results ($p < 0.001$) in the occurrence of primary outcomes supporting preventative PCI.

The primary outcomes were cardiac death, nonfatal myocardial infarction or refractory angina. At the conclusion of the study, primary outcomes had occurred in 9% of patients in the preventative PCI group and 23% of patients in the control group; this was an absolute risk reduction of 14% and a relative risk reduction of 65%. Individually, all primary outcomes were significant with similar risk reductions, even after excluding refractory angina as an end point.

The PRAMI trial demonstrated that a preventative PCI strategy significantly reduced the risk of cardiac death, nonfatal myocardial infarction or refractory angina. The risk reduction was evident at 6 months and was maintained throughout the study. However, the lack of a double-blind design may have led to bias in the study. Further research is needed to address whether these results can be more broadly applied and whether a staged approach to revascularization also has a benefit.

Saphenous vein coronary bypass interventions: first- and second-generation drug-eluting stent comparison

Evaluation of: Costopoulos C, Latib A, Naganuma T *et al.* Comparison of first- and second-generation drug-eluting stents in saphenous vein grafts used as aorto-coronary conduits. *Am. J. Cardiol.* 112, 318–322 (2013).

Saphenous vein grafts are commonly used in coronary artery bypass. However, they have a high rate of occlusion: 45% at 5 years. Repeat surgery poses high risk; therefore, percutaneous intervention has been the mainstay of treatment. Small, randomized trials and meta-analyses have favored the use of drug-eluting stents over bare-metal stents. In recent years there have been advances in stent technology. This study compares first- and second-generation drug-eluting stents in saphenous vein coronary bypasses.

This study by Costopoulos *et al.* was a retrospective analysis. They compared consecutive patients from April 2002 to March 2006 who received a paclitaxel- or sirolimus-eluting stent (first generation) with consecutive patients from January 2005 to April 2011 who received either an everolimus- or zotaroimus-eluting stent (second-generation) that had follow-up for at least 18 months. They identified 127 patients in the first-generation drug-eluting stents group and 84 patients in the second-generation drug-eluting stents group. The end points measured were all-cause death, myocardial infarction and target-vessel revascularization.

Baseline characteristics between the two groups were similar, except that the second-generation group tended to have older grafts, shorter stent length and smaller maximum balloon diameter. Futhermore, the second-generation group had a larger number of embolization devices used. Patients were assessed at 30 days, 12 months and 18 months. At 18 months, there were no significant differences noted in outcomes between the two groups. The cumulative outcomes at 18 months were seen in 24.4% of patients in the first-generation group and 20.2% of patients in the second-generation group, which was nonsignificant. There was no significant difference in any of the individually measured outcomes of death, cardiac death, myocardial infarction, target-vessel revascularization or target-lesion revascularization.

The results of this study suggest that second-generation stents are noninferior to first-generation stents in saphenous vein grafts. Limitations of this study are the retrospective, nonrandomized design and the use of a historical control group. At the present time, there appear to be no differences in the choice of drug-eluting stent to treat saphenous vein grafts. Further research is needed to determine whether a difference becomes apparent at a longer follow-up time.